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December 2, 2003

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Robert E. Hanson

Mail Stop Appeal Brief-Patents
Commissioner for Patents
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Alexandria, VA 22313-1450

Re: *SN 10/000,311 "INBRED CORN LINE LH321" – William D. Griffith*
Our Ref. HFSC:010US; Client Ref. 51635

Commissioner:

Enclosed for filing in the above-referenced patent application is:

1. A Brief on Appeal (original and 2 copies);
2. A check in the amount of \$330.00 in payment of the required filing fee; and
3. A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

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Respectfully submitted,



Robert E. Hanson
Reg. No. 42,628

REH/vv

Enclosures: As stated

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11/11/03

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
William D. Griffith

Serial No. 10/000,311

Filed: December 4, 2001

Title: INBRED CORN LINE LH321

Group Art Unit: 1638

Examiner: Fox, D.

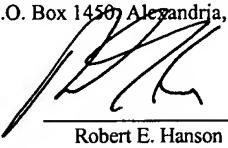
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December 2, 2003

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Robert E. Hanson

BRIEF ON APPEAL

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William D. Griffith

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Title: INBRED CORN LINE LH321

Group Art Unit: 1638

Examiner: Fox, D.

Atty. Dkt. No.: HFSC:010US
(formerly N1806-072)

BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Appeal Brief. The date for filing the instant Brief is December 2, 2003, based on the receipt of the Notice of Appeal by the Patent and Trademark Office on October 2, 2003. The fee for filing this Appeal Brief is attached herewith. No additional fees are believed due in connection with the instant paper. However, should any fees be due, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/HFSC:010US. Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. **REAL PARTIES IN INTEREST**

The real party in interest is Monsanto Company, the parent company of wholly-owned subsidiary Holden's Foundation Seed, Inc., the assignee of this application.

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II. RELATED APPEALS AND INTERFERENCES

Appeals have been filed in U.S. Patent Application Ser. No. 09/606,808; U.S. Patent Application Ser. No. 09/772,520; U.S. Patent Application Ser. No. 09/788,334; U.S. Patent Application Ser. No. 10/077,591; and U.S. Patent Application Ser. No. 10/077,589 on behalf of different wholly owned subsidiary of the Real Party in Interest. These cases also concern inbred corn plants. Although many of the claims are different, some of the same issues are raised in these cases as the instant appeal and therefore these appeals may have a bearing on the Board's decision in this case.

III. STATUS OF THE CLAIMS

Claims 1-32 were filed with the application. Claims 20, 22-23, 25, 29 and 32 were cancelled in the Amendment and Response filed April 14, 2003. Claims 1-19, 21, 24, 26-28, and 30-31 were therefore pending at the time of the final Office Action. Claims 1-5, 7, and 9-11 were allowed in the final Office Action and claims 6, 8, 12-19, 21, 24, 26-28, and 30-31 were rejected. The final rejection of claims 6, 12-19, 21, 24, 26-28, and 30-31 is the subject of the instant Appeal. A copy of the appealed claims is attached as Appendix 1. A copy of the pending claims is attached as Appendix 2.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the final Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn line designated LH321 and seeds or populations of seed thereof. Specification at page 6, paragraph 0023. The invention also relates to plants of LH321 comprising a gene conferring male sterility. Specification at page 7,

paragraph 0026. The invention further relates to plants of LH321 comprising one or more transgenes. Specification at page 28, paragraphs 0130-0131. The invention still further relates to methods comprising breeding LH321 with other corn plants, and hybrid plants produced thereby. Specification page 13, paragraph 0061.

VI. ISSUES ON APPEAL

- (1) Were claims 6, 12-19, 21, 24, 26-28 and 30-31 properly rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey that the Appellants were in possession of the claimed invention?
- (2) Were claims 6, 12-19, 21, 24, 26-28 and 30-31 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled?
- (3) Were claims 6 and 26-28 properly rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which Appellants regard as the invention?

VII. GROUPING OF THE CLAIMS

The claims stand or fall separately. The claims are directed to methods and compositions covering differing subject matter with progressively narrower scope. Distinct issues are therefore presented under the written description and enablement requirements.

VIII. SUMMARY OF THE ARGUMENT

The written description rejections fail because the claimed subject matter has been fully described. Each of the claimed hybrid plants and seeds having inbred corn plant LH321 as one parent have as half of their genome the same genetic contribution from LH321, given that corn plant LH321 is inbred. This structural characteristic is readily detectable and thus defines the claimed plants. These plants can be produced using any second plant, thus written description

with regard to the second parent is satisfied based on the countless corn varieties known to those of skill in the art, including the more than 300 corn varieties for which utility patents have previously been issued. Methods of crossing the claimed corn variety have been fully described in the recited steps, and such corn breeding steps were well known in the art. LH321 comprising transgenes were also fully described, in that well more than a representative collection of transgenes are described in the specification and were well known to those of skill in the art. The transgenes themselves are further not being claimed, rather it is corn plant LH321 comprising any given transgene that is claimed.

The enablement rejections fail because Appellants working examples and descriptions in the specification fully enable the claimed subject matter. The Examiner has improperly disregarded this evidence and failed to support the rejections in contradiction to the standards of the APA.

The indefiniteness rejections fail because the rejected claims are in proper dependent form. The claims incorporate all limitations of the claim from which they depend and add a further element. The claims are therefore fully definite.

IX. ARGUMENT

Appellants respectfully request that the Board reverse the rejections for the reasons set forth below.

A. **The Claims Are Fully Supported by a Written Description Pursuant to 35 U.S.C. §112, First Paragraph**

The Examiner rejects claims 6, 12-19, 21, 24, 26-28 and 30-31 under 35 U.S.C. §112, first paragraph, for allegedly lacking an adequate written description in the specification. In particular, it is alleged that written description is lacking for plants of corn line LH321

comprising a gene conferring male sterility, hybrid plants and seeds produced using corn line LH321 as one parent, methods of crossing corn line LH321 according to recited methods and methods of introducing a transgene into corn line LH321 and plants made therefrom.

1. Male Sterile and Transgenic Plants of Corn Line LH321 Are Described

The Examiner rejects claims directed to the corn plant of claim 2 further comprising a gene conferring male sterility or transgenes as lacking written description under 35 U.S.C. §112, first paragraph. The rejection is made based on the allegation that foreign genes and the phenotypes created therefrom have not been fully described.

Appellants note in response that the relevant claimed subject matter is the corn line LH321 comprising a gene conferring male sterility or transgenic versions of LH321. No specific phenotype is claimed. The transgenes *per se* are also not claimed and are well known to those of skill in the art. For example, nuclear and cytoplasmic genes conferring male sterility and introduction of these genes into corn varieties have been well known for many years (see, e.g., U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242).

The Examiner nonetheless alleges that Appellants have not described the full genus of transgenes for preparation of claimed plants. However, the Examiner has ignored Appellants evidence submitted in the prior response to office action and also recited in the specification showing numerous transgenes that were described. Among examples in the specification and the associated phenotypic traits described in the specification include the following: genes that confer resistance to herbicides or antibiotics such as (a) a neomycin phosphotransferase II (nptII) gene, isolated from transposon Tn5, conferring resistance to kanamycin, (b) a hygromycin phosphotransferase gene conferring resistance to the antibiotic hygromycin, (c) streptomycin

phosphotransferase, gentamycin acetyl transferase and aminoglycoside-3'-adenyl transferase, conferring resistance to antibiotics; screenable marker genes including, (a) β -glucuronidase, (b) luciferase, (c) chloramphenicol acetyltransferase, and (d) Green Fluorescent Protein (GFP); genes that confer resistance to pests or disease including (a) the tomato Cf-9 gene for resistance to *Cladosporium fulvum*, (b) the tomato Pto gene for resistance to *Pseudomonas syringae* pv., (c) an *Arabidopsis* RSP2 gene for resistance to *Pseudomonas syringae*, (d) a *Bacillus thuringiensis* insecticidal protein gene, (e) a vitamin-binding protein such as avidin, (f) an enzyme inhibitor, for example, a protease or proteinase inhibitor or an amylase inhibitor, and (g) an insect-specific hormone or pheromone such as an ecdysteroid and juvenile hormone; a mutant 5-enolpyruvl-3-phosphikimate synthase (EPSP) or aroA gene conferring resistance to glyphosate; antisense stearyl-ACP desaturase to increase stearic acid content of the plant; a phytase-encoding gene enhancing breakdown of phytate, adding more free phosphate to the transformed plant; and a gene coding for an enzyme that alters the branching pattern of starch such as an α -amylase or tomato invertase gene. Appellants could describe many more examples of potential transgenes that were well known as of the filing date, and would be glad to do so should the Board find it useful. It thus goes without saying that transgenes were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

As indicated in the specification, techniques for the introduction of transgenes by genetic transformation were further well known to those of skill in the art, including electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No. 5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon

carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). As also indicated in the specification, introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental procedures in agricultural science. With regard to the Examiner's allegations concerning the phenotype conferred by transgenes, it is noted that the claims do not require a particular phenotype.

Appellants have therefore shown possession of the claimed plants of line LH321 comprising transgenes and genes conferring male sterility. Both large numbers of male sterility genes and transgenes were well known to those of skill in the art as were methods for introduction thereof. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Appellants respectfully request reversal of the rejection.

2. Hybrid plants have been fully described

a. The claimed hybrid plants share the genetic complement of corn line LH321

The Examiner alleges that hybrid plants and seeds produced with corn plant LH321 as one parent and related methods were not adequately described. However, Appellants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the specification, corn plant LH321 is an inbred corn plant. All of the claimed hybrid plants having LH321 as a parent will therefore contain a copy of the same genome as corn plant LH321. That is, because LH321 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant LH321, save the possibility of the rare spontaneous mutation or undetected segregating locus. This *entire genetic contribution* of corn plant LH321 is *described*

in the specification by way of the proffered deposit of seed with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where “it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*” (emphasis added)). Here, all of the members of the claimed genus of hybrids having LH321 as one parent share the structural feature of having the genetic complement of LH321. One of skill in the art could thus readily identify the members of the genus.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant LH321 is crossed with a second plant. That is, any different second plant that is fertile, which corn plants naturally are, can be used to make the hybrid plant. Appellants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the

claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals more than 300 utility patents issued on different corn varieties issued prior to the filing date of the current application. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn line LH321 as one parent, and each of these would share the genetic complement of LH321.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As *any* second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Appellants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

b. The entire genetic complement is described by way of the proffered deposit of seed

The Examiner alleges that Appellants have not disclosed the genetic complement of the variety that is shared by each of the claimed hybrid plants and seeds. It is thus alleged that the genetic contribution of line LH321 could not be distinguished and is not described. This is incorrect, however, as Appellants describe the entire genetic sequence of line LH321 by way of a deposit of seed of the variety.

The Federal Circuit has recently held that a biological deposit may be used to satisfy written description for nucleic acids, whether the nucleic acid sequence is set forth in the specification or not. Specifically, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, the patent owner had

deposited six strains of *N. gonorrhoeae* and claimed nucleotide sequences hybridizing to the nucleic acids of these strains, but the patent application did not set forth the nucleic acid sequences of these strains in the specification. 296 F.3d 1316, 1328 (Fed. Cir. 2002). The Federal Circuit nonetheless held that “as those bacteria were deposited, their *bacterial genome is accessible* and, under our holding today, they are *adequately described in the specification by their accession numbers.*” (emphasis added) *Id.* In its holding, the Federal Circuit considered the burden that would be placed on applicants were they required to sequence each of the strains, noting lower court findings that it would have taken 3,000 scientists a month to sequence the bacterial genome of one strain of *N. gonorrhoeae*. *Id.* In the instant case, even more effort would be required, as corn is a higher life form with a more complex genome than the bacteria deposited in *Enzo*. The Examiner would nonetheless appear to require this much of Appellants in direct contradiction of *Enzo*.

The fact that the deposit here will be made after the filing date of the application has no bearing on written description, as the Federal Circuit has noted that insertion of an accession number for a deposit after the filing date adds no new matter to a case provided the deposited subject matter is clearly identified in the application. See *In re Lundak*, 773 F.2d 1216, 1217 (Fed. Cir. 1985) (“....an accession number and deposit date add nothing to the written description of the invention”). Appellants have therefore fully described the shared structure of the claimed hybrid plants at the nucleic acid level and thus have fully complied with 35 U.S.C. §112, first paragraph.

c. The Examiner’s allegations that the expression of the genetic complement of corn line LH321 is unpredictable are inapposite

The Examiner alleges that claimed hybrid plants have not been described despite inheriting the genetic complement of line LH321 because information is not provided regarding

the morphological and physiological traits of the hybrid plants. It is alleged that how the genes that are inherited would be expressed or would interact has not been shown. However, this misses the point that Appellants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the genetic level. A better description could not be made than at the genetic level. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing goes to the source of traits and yields concrete values.

The law makes no distinctions regarding the manner in which applicants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject matter by “whatever characteristics sufficiently distinguish it.” *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Appellants have described the entire genetic complement of parent plant LH321 that will be comprised in the claimed hybrid plants by way of the proffered seed deposit made with the ATCC. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002).

d. Appellants fully describe exemplary hybrids made using inbred LH321

The specification also describes four hybrids that were produced using LH321 as one parent in Tables 1-4. Shown in the tables are the mean yield, percentage moisture, stalk lodging, root lodging, percent of dropped ears, plant height and ear height for these hybrids. This information, combined with the descriptions of the genetic and morphological characteristics of LH321 in the specification, is more than adequate to provide a description of hybrid plants and seeds derived from corn plant LH321 in compliance with the written description requirement. While the claims are directed to a genus of plants, these four hybrids constitute a representative set of species describing the genus based on the shared structural characteristics of the members

of the genus. One of skill in the art could thus readily identify the members of the genus. The written description requirement has therefore been fully complied with.

3. The Method Claims Are Fully Described

The Examiner rejects claims 17-19, 21, 24, 27 and 30-31, which are method claims that involve breeding of corn plant LH321, as lacking written description. While the portion of the rejection applicable to these claims was not clearly delineated, it is believed that the claims have been rejected based on an alleged failure to describe starting plants and/or plants made at intermediate steps of the methods, as it has not been alleged that any essential steps are absent.

The claims fully describe all starting materials. The only starting materials required for the methods are: (1) corn line LH321, (2) *any* second corn plant, (3) *any* transgene, and (4) a corn plant that is produced by following a preceding method step. The method has therefore been fully described. The Examiner has already acknowledged that corn line LH321 has been described. As set forth above in detail above, transgenes and second corn plants generally have also been described, as no particular transgene or second plant is required for the claims. Finally, corn plants produced at intermediate steps in the methods are defined by and inherently produced by the claimed methods and are therefore also described.

With regard to the latter, it is believed that it is the position of the Examiner that each product produced at any intermediate or penultimate step of the method has not adequately described. Specifically, it is believed that it is the Examiner's position that intermediate products must be described as if claimed in a composition of matter claim. However, what is required to meet the written description requirement is that an Applicant show that he or she was in possession of the *claimed invention*. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Here, a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products of the steps. The starting materials

for the process must be provided, otherwise the process could not be completed. However, as set forth above, the starting materials have already been described. Any materials in the intermediate steps are produced by the preceding steps and indeed are defined by these steps. No basis for the rejection has therefore been provided.

The Examiner has cited the Written Description Guidelines, Fed. Reg. Vol. 66, pp1099-1111 (Jan. 5, 2001), as allegedly supporting the rejection. A review of this section finds no support for the position taken. It is respectfully submitted that the Guidelines have been applied by the Examiner in the context of product-by-process claims, not process claims. Nowhere does the comment state that process and composition claims are analyzed in the same manner. Indeed, Appellants note that the initial analysis of written description set forth under the Guidelines involves “(i) Determin[ing] whether the application as filed describes the complete structure (*or* acts of a *process*) of the claimed invention as a whole.” (emphasis added). Elsewhere in the guidelines the same distinction is made. The Guidelines therefore fail to support and contradict the position taken by the Examiner.

4. The Rejections Are Not Supported in Compliance With the APA

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act (“APA”). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko*, 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by “substantial evidence” within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner’s position on Appeal must be supported by “substantial evidence” within the record in order to be upheld by the Board of Patent Appeals and Interferences. As demonstrated above, the current rejections are unsupported in fact or law.

The standards of the APA have therefore not been met and reversal of the rejection is thus respectfully requested.

In conclusion, all of the claimed methods and starting materials were fully described. Reversal of the rejection is thus respectfully requested.

B. The Claims Are Enabled Under 35 U.S.C. §112, First Paragraph

The Examiner rejects claims 6, 12-19, 21, 24, 26-28 and 30-31 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. In particular, the Examiner alleges that the specification does not adequately describe the corn line LH321 comprising a transgene and methods of use thereof, production of hybrid plants and methods of corn breeding comprising use of corn line LH321.

The Examiner rejects claims directed to male sterile or transgenic plants and methods for production thereof as allegedly lacking enablement. However, the Examiner has acknowledged the enablement of corn line LH321 itself based on the lack of rejection of claims 1 and 2. The Examiner further acknowledges the ability to produce transgenic corn plants. The rejection of claims directed to transgenic plants and methods of production thereof was nonetheless maintained by the Examiner based on the allegation that it is unknown what the phenotype of any plants produced using “a multitude of non-exemplified transgenes” would be. However, the Examiner has failed to apply the enablement requirement with respect to the *claimed invention*.

None of the claims require that any given phenotype be conferred by a transgene or require that a specific transgene be introduced. Rather the point of novelty of the claims is the corn line LH321, not transgenes or methods of corn transformation, each of which were well

known. Any transgene may be introduced in accordance with the claimed invention. The specification describes numerous examples of coding and regulatory sequences that could be introduced into corn plant LH321 and many thousands of such genes were well known in the art. The Examiner has provided no basis to conclude why one of skill in the art could introduce only certain types of transgenes. Therefore, the Examiner's acknowledgement of enablement for transforming corn and for corn line LH321 demonstrates enablement of corn line LH321 transformed with one or more transgenes.

With regard to creation of male sterile plants, the Examiner acknowledges enablement of this subject matter by inviting Appellants to amend the claims to recite male sterile plants produced by transforming corn line LH321 with a nucleic acid molecule conferring male sterility. Creation of male-sterile plants is also a technique that has been *well-known for decades*, many years even before genetic transformation was known. This is evidenced by the numerous issued patents for creation of male sterile plants (see U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242). No reasonable basis has been provided as to why these well known techniques cannot be applied in the context of corn line LH321.

The only basis alleged by the Examiner for the rejection is several references said to show the difficulty of making male sterile or transgenic plants. However, these references have not been shown to have any relevance to *corn* plants beyond the mere opinion of the Examiner. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The relevance of the references to the claimed invention has therefore not been established, as is specifically required to demonstrate a *prima facie* case of non-enablement.

Corn breeding is extremely advanced and well known in the art. This is due in large part to the fact that corn is one of the world's major food crops and largest seed crops. North American farmers alone plant *tens of millions of acres* of corn at the present time and there are *extensive national and international commercial corn breeding* programs. It is respectfully submitted that this is not true of petunias, sugar beets and tomatoes.

The Examiner has also not provided any basis other than personal opinion to suggest why the genetics of any of petunias, sugar beets or tomatoes are relevant to corn. Each of these plants are widely genetically diverged from maize – they are each classified as dicotyledonous plants whereas maize is a monocotyledonous plant. This distinction was noted by the Federal Circuit in *Plant Genetic Systems v. DeKalb Genetics Corp.*, in which a finding on non-enablement was affirmed because the claims read on both monocotyledonous and dicotyledonous plants, but were only enabled for dicotyledonous plants. 315 F.3d 1335 (Fed. Cir. 2003).

It therefore appears that the Examiner has improperly placed the burden to show enablement on Appellants while doubting numerous lines of evidence in support of enablement. The indication that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support. At the same time, the Examiner attempts to require Appellants to show why this is not true. While Appellants have nonetheless done so, it is respectfully noted that it is the *Office* that bears the burden of supporting its rejections. Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act (“APA”). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko*, 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by “substantial evidence” within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir.

2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections are unsupported as required by the APA and contrary to the evidence submitted by Appellants.

The Examiner has also alleged that hybrid plants, seeds or parts thereof in claims 12-16 are not enabled. However, the Examiner has already acknowledged that the method of making a hybrid plant in claim 11 is enabled. Claim 12 is directed to the seed of claim 11. The rejection must therefore fail on its face – if the method of producing seed in claim 11 is enabled so is the seed produced by that method. Further, the specification describes *working examples* showing the production of *four hybrid plants*. No reason has been presented to conclude why this does not show enablement of the claims.

Claim 13 is directed to a plant produced by growing the seed of claim 12. As all that is required for this claim is mere germination of the seed in claim 12, this claim is also enabled. Claim 14 is directed to a seed produced by the plant of claim 13, which is inherently produced by growing the plant and is therefore also enabled.

Claim 15 is directed to an F1 hybrid plant produced by crossing the plant of claim 2 to *any* second plant. The plant of claim 2 has not been rejected and thus has been acknowledged to be enabled. All that the claim therefore requires is cross-pollinating the plant of claim 2 with any second plant. Once again, there is no basis to conclude why one of skill in the art could not do this, the most basic plant breeding step, particularly in light of the allowance of claim 11. Claim 16 is directed to a corn plant made by growing seed of claim 15, which again only requires germination of the seed and is enabled by claim 15.

All of the claims are therefore enabled and reversal of the rejection is thus respectfully requested.

Claims 17-18 concern a method for producing inbred LH321 seed comprising following the recited steps. Again, all that is required to complete the method is to follow the steps given in the claim, which themselves are known in the art and described in the specification. What was not known was the point of novelty, corn plant LH321, which has already been acknowledged to be enabled as set forth above. As such, the Examiner has failed to provide any basis to doubt the enablement of the claims.

Claims 19, 21, 24, 27 and 30-31 are all method claims that involve breeding corn plant corn plant LH321 according to the recited methods. Once again, all that is required to complete the method is to follow the steps given in the claim, which themselves are standard in the art. The only necessary starting material is corn plant LH321, which has already been acknowledged to be enabled as set forth above. While some of the steps involve use of a second corn plant, *any* different second corn plant can be used. What other plant or plants one chooses to cross with the claimed variety is therefore *completely irrelevant to enablement*, as any fertile corn plant could be used to produce an inbred corn plant derived from the corn line LH321. Enablement only requires that one of skill in the art be able to make and use the *claimed invention* without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). This has fully been done and no basis has been provided to conclude otherwise.

In view of the foregoing reversal of the rejection is respectfully requested.

C. **Claims 6 and 26-28 Are Definite Under 35 U.S.C. §112, Second Paragraph**

The Examiner rejects claims 6, 8 and 26-28 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out the subject matter which Applicants

regard as the invention. The rejection of claim 8 concerns a minor clerical error easily corrected by amendment and thus has not been appealed.

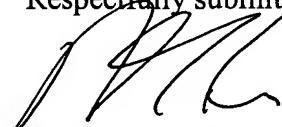
Claims 6 and 26-28 were rejected as allegedly broadening the scope of the claims from which they depend. In particular, it was stated that the independent claims from which these claims depend recite a plant with a given set of characteristics and claims 6 and 26-28 broaden this. However, this is incorrect. Both claims (1) *contain a reference to parent claim* from which they depend, (2) contain a *further limitation* of the subject matter claimed in the main claim, and (3) *incorporate all elements* of the claim from which they depend. For example, claim 6 recites the corn plant of claim 2 “further defined as comprising a gene conferring male sterility.” Claim 26, which claims 27 and 28 incorporate by reference, recites the corn plant of claim 2, “wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.”

Claims 6 and 26 therefore each specify an element that is *added* to the independent claim while still incorporating all of the limitations of the independent claim. Both claims are in proper dependent form pursuant to 37 C.F.R. §1.75(c) and are fully definite. Claims 27-28, which incorporate claim 26 by reference, are therefore also not indefinite. Reversal of the rejection is thus respectfully requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



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Date: December 2, 2003

APPENDIX 1: APPEALED CLAIMS

6. (Amended) The corn plant of claim 2, wherein said plant is further defined as comprising a gene conferring male sterility.
12. A hybrid corn seed produced by the method of claim 11.
13. A hybrid corn plant, or parts thereof, produced by growing said hybrid corn seed of claim 12.
14. A corn seed produced by growing said corn plant of claim 13 and harvesting the resultant corn seed.
15. An F₁ hybrid seed produced by crossing the inbred corn plant according to claim 2 with another, different corn plant.
16. A hybrid corn plant, or its parts, produced by growing said hybrid corn seed of claim 15.
17. (Amended) A method for producing inbred LH321 seed, representative seed of which have been deposited under ATCC Accession No. _____, comprising:
 - a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred LH321, said collection also comprising seed of said inbred;
 - b) growing plants from said collection of seed;
 - c) identifying inbred parent plants;
 - d) controlling pollination in a manner which preserves the homozygosity of said inbred parent plant; and
 - e) harvesting the resultant seed.
18. (Amended) The process of claim 17 wherein step (c) further comprises identifying plants with decreased vigor.
19. A method for producing a LH321-derived corn plant, comprising:
 - a) crossing inbred corn line LH321, representative seed of said line having been deposited under ATCC accession number _____, with a second corn plant to yield progeny corn seed; and
 - b) growing said progeny corn seed, under plant growth conditions, to yield said LH321-derived corn plant.
21. The method of claim 19, further comprising:
 - c) crossing said LH321-derived corn plant with itself or another corn plant to yield additional LH321-derived progeny corn seed;

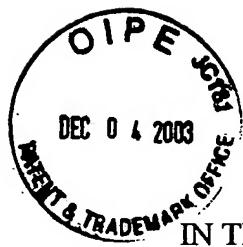
- d) growing said progeny corn seed of step (c) under plant growth conditions, to yield additional LH321-derived corn plants; and
 - e) repeating the crossing and growing steps of (c) and (d) from 0 to 7 times to generate further LH321-derived corn plants.
24. The method of claim 19, still further comprising utilizing plant tissue culture methods to derive progeny of said LH321-derived corn plant.
26. The corn plant, or parts thereof, of claim 2, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.
27. (Amended) A method for producing a corn plant that contains in its genetic material one or more transgenes, comprising crossing the corn plant of claim 26 with either a second plant of another corn line, or a non-transformed corn plant of the line LH321, wherein progeny are produced, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element.
28. Corn plants, or parts thereof, produced by the method of claim 27.
30. (Amended) A method for developing a corn plant in a corn plant breeding program using plant breeding techniques comprising employing a corn plant, or its parts, as a source of plant breeding material comprising: using the corn plant, or its parts, of claim 2 as a source of said breeding material.
31. (Amended) The method for developing a corn plant in a corn plant breeding program of claim 30 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.

APPENDIX 2: PENDING CLAIMS

1. Seed of corn inbred line designated LH321, representative seed of said line having been deposited under ATCC Accession No. _____.
2. A corn plant, or parts thereof, produced by growing the seed of claim 1.
3. Pollen of the plant of claim 2.
4. An ovule of the plant of claim 2.
5. A corn plant, or parts thereof, having all of the physiological and morphological characteristics of the corn plant of claim 2.
6. (Amended) The corn plant of claim 2, wherein said plant is further defined as comprising a gene conferring male sterility.
7. A tissue culture of regenerable cells from the corn plant of claim 2.
8. (Amended) The tissue culture according to claim 7, the cells or protoplasts of the tissue culture having been isolated from a tissue selected from the group consisting of leaves, pollen, embryos, roots, root tips, anthers, silks, flowers, kernels, ears, cobs, husks, and stalks.
9. (Amended) A corn plant regenerated from the tissue culture of claim 7, wherein the regenerated plant expresses all the morphological and physiological characteristics of inbred line LH321.
10. (Amended) A corn plant with all of the physiological and morphological characteristics of corn inbred LH321, wherein said corn plant is produced by a tissue culture process using the corn plant of claim 5 as the starting material for said process.
11. A method for producing a hybrid corn seed comprising crossing a first inbred parent corn plant with a second inbred parent corn plant and harvesting the resultant hybrid corn seed, wherein said first inbred parent corn plant or second said parent corn plant is the corn plant of claim 2.
12. A hybrid corn seed produced by the method of claim 11.
13. A hybrid corn plant, or parts thereof, produced by growing said hybrid corn seed of claim 12.
14. A corn seed produced by growing said corn plant of claim 13 and harvesting the resultant corn seed.

15. An F₁ hybrid seed produced by crossing the inbred corn plant according to claim 2 with another, different corn plant.
16. A hybrid corn plant, or its parts, produced by growing said hybrid corn seed of claim 15.
17. (Amended) A method for producing inbred LH321 seed, representative seed of which have been deposited under ATCC Accession No. _____, comprising:
 - a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred LH321, said collection also comprising seed of said inbred;
 - b) growing plants from said collection of seed;
 - c) identifying inbred parent plants;
 - d) controlling pollination in a manner which preserves the homozygosity of said inbred parent plant; and
 - e) harvesting the resultant seed.
18. (Amended) The process of claim 17 wherein step (c) further comprises identifying plants with decreased vigor.
19. A method for producing a LH321-derived corn plant, comprising:
 - a) crossing inbred corn line LH321, representative seed of said line having been deposited under ATCC accession number _____, with a second corn plant to yield progeny corn seed; and
 - b) growing said progeny corn seed, under plant growth conditions, to yield said LH321-derived corn plant.
21. The method of claim 19, further comprising:
 - c) crossing said LH321-derived corn plant with itself or another corn plant to yield additional LH321-derived progeny corn seed;
 - d) growing said progeny corn seed of step (c) under plant growth conditions, to yield additional LH321-derived corn plants; and
 - e) repeating the crossing and growing steps of (c) and (d) from 0 to 7 times to generate further LH321-derived corn plants.
24. The method of claim 19, still further comprising utilizing plant tissue culture methods to derive progeny of said LH321-derived corn plant.

26. The corn plant, or parts thereof, of claim 2, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.
27. (Amended) A method for producing a corn plant that contains in its genetic material one or more transgenes, comprising crossing the corn plant of claim 26 with either a second plant of another corn line, or a non-transformed corn plant of the line LH321, wherein progeny are produced, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element.
28. Corn plants, or parts thereof, produced by the method of claim 27.
30. (Amended) A method for developing a corn plant in a corn plant breeding program using plant breeding techniques comprising employing a corn plant, or its parts, as a source of plant breeding material comprising: using the corn plant, or its parts, of claim 2 as a source of said breeding material.
31. (Amended) The method for developing a corn plant in a corn plant breeding program of claim 30 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
William D. Griffith

Serial No. 10/000,311

Filed: December 4, 2001

Title: INBRED CORN LINE LH321

Group Art Unit: 1638

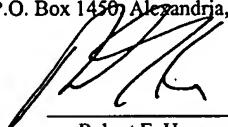
Examiner: Fox, D.

Atty. Dkt. No.: HFSC:010US

CERTIFICATE OF MAILING
37 C.F.R. §1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

December 2, 2003
Date


Robert E. Hanson

BRIEF ON APPEAL

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Group Art Unit: 1638

Examiner: Fox, D.

Atty. Dkt. No.: HFSC:010US
(formerly N1806-072)

BRIEF ON APPEAL

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Appeal Brief. The date for filing the instant Brief is December 2, 2003, based on the receipt of the Notice of Appeal by the Patent and Trademark Office on October 2, 2003. The fee for filing this Appeal Brief is attached herewith. No additional fees are believed due in connection with the instant paper. However, should any fees be due, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/HFSC:010US. Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent company of wholly-owned subsidiary Holden's Foundation Seed, Inc., the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

Appeals have been filed in U.S. Patent Application Ser. No. 09/606,808; U.S. Patent Application Ser. No. 09/772,520; U.S. Patent Application Ser. No. 09/788,334; U.S. Patent Application Ser. No. 10/077,591; and U.S. Patent Application Ser. No. 10/077,589 on behalf of different wholly owned subsidiary of the Real Party in Interest. These cases also concern inbred corn plants. Although many of the claims are different, some of the same issues are raised in these cases as the instant appeal and therefore these appeals may have a bearing on the Board's decision in this case.

III. STATUS OF THE CLAIMS

Claims 1-32 were filed with the application. Claims 20, 22-23, 25, 29 and 32 were cancelled in the Amendment and Response filed April 14, 2003. Claims 1-19, 21, 24, 26-28, and 30-31 were therefore pending at the time of the final Office Action. Claims 1-5, 7, and 9-11 were allowed in the final Office Action and claims 6, 8, 12-19, 21, 24, 26-28, and 30-31 were rejected. The final rejection of claims 6, 12-19, 21, 24, 26-28, and 30-31 is the subject of the instant Appeal. A copy of the appealed claims is attached as Appendix 1. A copy of the pending claims is attached as Appendix 2.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the final Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn line designated LH321 and seeds or populations of seed thereof. Specification at page 6, paragraph 0023. The invention also relates to plants of LH321 comprising a gene conferring male sterility. Specification at page 7,

paragraph 0026. The invention further relates to plants of LH321 comprising one or more transgenes. Specification at page 28, paragraphs 0130-0131. The invention still further relates to methods comprising breeding LH321 with other corn plants, and hybrid plants produced thereby. Specification page 13, paragraph 0061.

VI. ISSUES ON APPEAL

(1) Were claims 6, 12-19, 21, 24, 26-28 and 30-31 properly rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey that the Appellants were in possession of the claimed invention?

(2) Were claims 6, 12-19, 21, 24, 26-28 and 30-31 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled?

(3) Were claims 6 and 26-28 properly rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which Appellants regard as the invention?

VII. GROUPING OF THE CLAIMS

The claims stand or fall separately. The claims are directed to methods and compositions covering differing subject matter with progressively narrower scope. Distinct issues are therefore presented under the written description and enablement requirements.

VIII. SUMMARY OF THE ARGUMENT

The written description rejections fail because the claimed subject matter has been fully described. Each of the claimed hybrid plants and seeds having inbred corn plant LH321 as one parent have as half of their genome the same genetic contribution from LH321, given that corn plant LH321 is inbred. This structural characteristic is readily detectable and thus defines the claimed plants. These plants can be produced using any second plant, thus written description

with regard to the second parent is satisfied based on the countless corn varieties known to those of skill in the art, including the more than 300 corn varieties for which utility patents have previously been issued. Methods of crossing the claimed corn variety have been fully described in the recited steps, and such corn breeding steps were well known in the art. LH321 comprising transgenes were also fully described, in that well more than a representative collection of transgenes are described in the specification and were well known to those of skill in the art. The transgenes themselves are further not being claimed, rather it is corn plant LH321 comprising any given transgene that is claimed.

The enablement rejections fail because Appellants working examples and descriptions in the specification fully enable the claimed subject matter. The Examiner has improperly disregarded this evidence and failed to support the rejections in contradiction to the standards of the APA.

The indefiniteness rejections fail because the rejected claims are in proper dependent form. The claims incorporate all limitations of the claim from which they depend and add a further element. The claims are therefore fully definite.

IX. ARGUMENT

Appellants respectfully request that the Board reverse the rejections for the reasons set forth below.

A. **The Claims Are Fully Supported by a Written Description Pursuant to 35 U.S.C. §112, First Paragraph**

The Examiner rejects claims 6, 12-19, 21, 24, 26-28 and 30-31 under 35 U.S.C. §112, first paragraph, for allegedly lacking an adequate written description in the specification. In particular, it is alleged that written description is lacking for plants of corn line LH321

comprising a gene conferring male sterility, hybrid plants and seeds produced using corn line LH321 as one parent, methods of crossing corn line LH321 according to recited methods and methods of introducing a transgene into corn line LH321 and plants made therefrom.

1. Male Sterile and Transgenic Plants of Corn Line LH321 Are Described

The Examiner rejects claims directed to the corn plant of claim 2 further comprising a gene conferring male sterility or transgenes as lacking written description under 35 U.S.C. §112, first paragraph. The rejection is made based on the allegation that foreign genes and the phenotypes created therefrom have not been fully described.

Appellants note in response that the relevant claimed subject matter is the corn line LH321 comprising a gene conferring male sterility or transgenic versions of LH321. No specific phenotype is claimed. The transgenes *per se* are also not claimed and are well known to those of skill in the art. For example, nuclear and cytoplasmic genes conferring male sterility and introduction of these genes into corn varieties have been well known for many years (see, e.g., U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242).

The Examiner nonetheless alleges that Appellants have not described the full genus of transgenes for preparation of claimed plants. However, the Examiner has ignored Appellants evidence submitted in the prior response to office action and also recited in the specification showing numerous transgenes that were described. Among examples in the specification and the associated phenotypic traits described in the specification include the following: genes that confer resistance to herbicides or antibiotics such as (a) a neomycin phosphotransferase II (*nptII*) gene, isolated from transposon Tn5, conferring resistance to kanamycin, (b) a hygromycin phosphotransferase gene conferring resistance to the antibiotic hygromycin, (c) streptomycin

phosphotransferase, gentamycin acetyl transferase and aminoglycoside-3'-adenyl transferase, conferring resistance to antibiotics; screenable marker genes including, (a) β -glucuronidase, (b) luciferase, (c) chloramphenicol acetyltransferase, and (d) Green Fluorescent Protein (GFP); genes that confer resistance to pests or disease including (a) the tomato Cf-9 gene for resistance to *Cladosporium fulvum*, (b) the tomato Pto gene for resistance to *Pseudomonas syringae* pv., (c) an *Arabidopsis* RSP2 gene for resistance to *Pseudomonas syringae*, (d) a *Bacillus thuringiensis* insecticidal protein gene, (e) a vitamin-binding protein such as avidin, (f) an enzyme inhibitor, for example, a protease or proteinase inhibitor or an amylase inhibitor, and (g) an insect-specific hormone or pheromone such as an ecdysteroid and juvenile hormone; a mutant 5-enolpyruvl-3-phosphikimate synthase (EPSP) or aroA gene conferring resistance to glyphosate; antisense stearyl-ACP desaturase to increase stearic acid content of the plant; a phytase-encoding gene enhancing breakdown of phytate, adding more free phosphate to the transformed plant; and a gene coding for an enzyme that alters the branching pattern of starch such as an α -amylase or tomato invertase gene. Appellants could describe many more examples of potential transgenes that were well known as of the filing date, and would be glad to do so should the Board find it useful. It thus goes without saying that transgenes were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

As indicated in the specification, techniques for the introduction of transgenes by genetic transformation were further well known to those of skill in the art, including electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No. 5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon

carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). As also indicated in the specification, introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental procedures in agricultural science. With regard to the Examiner's allegations concerning the phenotype conferred by transgenes, it is noted that the claims do not require a particular phenotype.

Appellants have therefore shown possession of the claimed plants of line LH321 comprising transgenes and genes conferring male sterility. Both large numbers of male sterility genes and transgenes were well known to those of skill in the art as were methods for introduction thereof. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Appellants respectfully request reversal of the rejection.

2. **Hybrid plants have been fully described**

a. **The claimed hybrid plants share the genetic complement of corn line LH321**

The Examiner alleges that hybrid plants and seeds produced with corn plant LH321 as one parent and related methods were not adequately described. However, Appellants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the specification, corn plant LH321 is an inbred corn plant. All of the claimed hybrid plants having LH321 as a parent will therefore contain a copy of the same genome as corn plant LH321. That is, because LH321 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant LH321, save the possibility of the rare spontaneous mutation or undetected segregating locus. This *entire genetic contribution* of corn plant LH321 is *described*

in the specification by way of the proffered deposit of seed with the ATCC. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where “it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*” (emphasis added)). Here, all of the members of the claimed genus of hybrids having LH321 as one parent share the structural feature of having the genetic complement of LH321. One of skill in the art could thus readily identify the members of the genus.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant LH321 is crossed with a second plant. That is, any different second plant that is fertile, which corn plants naturally are, can be used to make the hybrid plant. Appellants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the

claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals more than 300 utility patents issued on different corn varieties issued prior to the filing date of the current application. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn line LH321 as one parent, and each of these would share the genetic complement of LH321.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As *any* second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Appellants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

b. The entire genetic complement is described by way of the proffered deposit of seed

The Examiner alleges that Appellants have not disclosed the genetic complement of the variety that is shared by each of the claimed hybrid plants and seeds. It is thus alleged that the genetic contribution of line LH321 could not be distinguished and is not described. This is incorrect, however, as Appellants describe the entire genetic sequence of line LH321 by way of a deposit of seed of the variety.

The Federal Circuit has recently held that a biological deposit may be used to satisfy written description for nucleic acids, whether the nucleic acid sequence is set forth in the specification or not. Specifically, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, the patent owner had

deposited six strains of *N. gonorrhoeae* and claimed nucleotide sequences hybridizing to the nucleic acids of these strains, but the patent application did not set forth the nucleic acid sequences of these strains in the specification. 296 F.3d 1316, 1328 (Fed. Cir. 2002). The Federal Circuit nonetheless held that “as those bacteria were deposited, their *bacterial genome is accessible* and, under our holding today, they are *adequately described in the specification by their accession numbers.*” (emphasis added) *Id.* In its holding, the Federal Circuit considered the burden that would be placed on applicants were they required to sequence each of the strains, noting lower court findings that it would have taken 3,000 scientists a month to sequence the bacterial genome of one strain of *N. gonorrhoeae*. *Id.* In the instant case, even more effort would be required, as corn is a higher life form with a more complex genome than the bacteria deposited in *Enzo*. The Examiner would nonetheless appear to require this much of Appellants in direct contradiction of *Enzo*.

The fact that the deposit here will be made after the filing date of the application has no bearing on written description, as the Federal Circuit has noted that insertion of an accession number for a deposit after the filing date adds no new matter to a case provided the deposited subject matter is clearly identified in the application. See *In re Lundak*, 773 F.2d 1216, 1217 (Fed. Cir. 1985) ("....an accession number and deposit date add nothing to the written description of the invention"). Appellants have therefore fully described the shared structure of the claimed hybrid plants at the nucleic acid level and thus have fully complied with 35 U.S.C. §112, first paragraph.

c. The Examiner's allegations that the expression of the genetic complement of corn line LH321 is unpredictable are inapposite

The Examiner alleges that claimed hybrid plants have not been described despite inheriting the genetic complement of line LH321 because information is not provided regarding

the morphological and physiological traits of the hybrid plants. It is alleged that how the genes that are inherited would be expressed or would interact has not been shown. However, this misses the point that Appellants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the genetic level. A better description could not be made than at the genetic level. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing goes to the source of traits and yields concrete values.

The law makes no distinctions regarding the manner in which applicants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject matter by “whatever characteristics sufficiently distinguish it.” *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Appellants have described the entire genetic complement of parent plant LH321 that will be comprised in the claimed hybrid plants by way of the proffered seed deposit made with the ATCC. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002).

d. Appellants fully describe exemplary hybrids made using inbred LH321

The specification also describes four hybrids that were produced using LH321 as one parent in Tables 1-4. Shown in the tables are the mean yield, percentage moisture, stalk lodging, root lodging, percent of dropped ears, plant height and ear height for these hybrids. This information, combined with the descriptions of the genetic and morphological characteristics of LH321 in the specification, is more than adequate to provide a description of hybrid plants and seeds derived from corn plant LH321 in compliance with the written description requirement. While the claims are directed to a genus of plants, these four hybrids constitute a representative set of species describing the genus based on the shared structural characteristics of the members

of the genus. One of skill in the art could thus readily identify the members of the genus. The written description requirement has therefore been fully complied with.

3. The Method Claims Are Fully Described

The Examiner rejects claims 17-19, 21, 24, 27 and 30-31, which are method claims that involve breeding of corn plant LH321, as lacking written description. While the portion of the rejection applicable to these claims was not clearly delineated, it is believed that the claims have been rejected based on an alleged failure to describe starting plants and/or plants made at intermediate steps of the methods, as it has not been alleged that any essential steps are absent.

The claims fully describe all starting materials. The only starting materials required for the methods are: (1) corn line LH321, (2) *any* second corn plant, (3) *any* transgene, and (4) a corn plant that is produced by following a preceding method step. The method has therefore been fully described. The Examiner has already acknowledged that corn line LH321 has been described. As set forth above in detail above, transgenes and second corn plants generally have also been described, as no particular transgene or second plant is required for the claims. Finally, corn plants produced at intermediate steps in the methods are defined by and inherently produced by the claimed methods and are therefore also described.

With regard to the latter, it is believed that it is the position of the Examiner that each product produced at any intermediate or penultimate step of the method has not adequately described. Specifically, it is believed that it is the Examiner's position that intermediate products must be described as if claimed in a composition of matter claim. However, what is required to meet the written description requirement is that an Applicant show that he or she was in possession of the *claimed invention*. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Here, a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products of the steps. The starting materials

for the process must be provided, otherwise the process could not be completed. However, as set forth above, the starting materials have already been described. Any materials in the intermediate steps are produced by the preceding steps and indeed are defined by these steps. No basis for the rejection has therefore been provided.

The Examiner has cited the Written Description Guidelines, Fed. Reg. Vol. 66, pp1099-1111 (Jan. 5, 2001), as allegedly supporting the rejection. A review of this section finds no support for the position taken. It is respectfully submitted that the Guidelines have been applied by the Examiner in the context of product-by-process claims, not process claims. Nowhere does the comment state that process and composition claims are analyzed in the same manner. Indeed, Appellants note that the initial analysis of written description set forth under the Guidelines involves “(i) Determin[ing] whether the application as filed describes the complete structure (*or acts of a process*) of the claimed invention as a whole.” (emphasis added). Elsewhere in the guidelines the same distinction is made. The Guidelines therefore fail to support and contradict the position taken by the Examiner.

4. The Rejections Are Not Supported in Compliance With the APA

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act (“APA”). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko*, 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by “substantial evidence” within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner’s position on Appeal must be supported by “substantial evidence” within the record in order to be upheld by the Board of Patent Appeals and Interferences. As demonstrated above, the current rejections are unsupported in fact or law.

The standards of the APA have therefore not been met and reversal of the rejection is thus respectfully requested.

In conclusion, all of the claimed methods and starting materials were fully described. Reversal of the rejection is thus respectfully requested.

B. The Claims Are Enabled Under 35 U.S.C. §112, First Paragraph

The Examiner rejects claims 6, 12-19, 21, 24, 26-28 and 30-31 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. In particular, the Examiner alleges that the specification does not adequately describe the corn line LH321 comprising a transgene and methods of use thereof, production of hybrid plants and methods of corn breeding comprising use of corn line LH321.

The Examiner rejects claims directed to male sterile or transgenic plants and methods for production thereof as allegedly lacking enablement. However, the Examiner has acknowledged the enablement of corn line LH321 itself based on the lack of rejection of claims 1 and 2. The Examiner further acknowledges the ability to produce transgenic corn plants. The rejection of claims directed to transgenic plants and methods of production thereof was nonetheless maintained by the Examiner based on the allegation that it is unknown what the phenotype of any plants produced using “a multitude of non-exemplified transgenes” would be. However, the Examiner has failed to apply the enablement requirement with respect to the *claimed invention*.

None of the claims require that any given phenotype be conferred by a transgene or require that a specific transgene be introduced. Rather the point of novelty of the claims is the corn line LH321, not transgenes or methods of corn transformation, each of which were well

known. Any transgene may be introduced in accordance with the claimed invention. The specification describes numerous examples of coding and regulatory sequences that could be introduced into corn plant LH321 and many thousands of such genes were well known in the art. The Examiner has provided no basis to conclude why one of skill in the art could introduce only certain types of transgenes. Therefore, the Examiner's acknowledgement of enablement for transforming corn and for corn line LH321 demonstrates enablement of corn line LH321 transformed with one or more transgenes.

With regard to creation of male sterile plants, the Examiner acknowledges enablement of this subject matter by inviting Appellants to amend the claims to recite male sterile plants produced by transforming corn line LH321 with a nucleic acid molecule conferring male sterility. Creation of male-sterile plants is also a technique that has been *well-known for decades*, many years even before genetic transformation was known. This is evidenced by the numerous issued patents for creation of male sterile plants (see U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242). No reasonable basis has been provided as to why these well known techniques cannot be applied in the context of corn line LH321.

The only basis alleged by the Examiner for the rejection is several references said to show the difficulty of making male sterile or transgenic plants. However, these references have not been shown to have any relevance to *corn* plants beyond the mere opinion of the Examiner. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The relevance of the references to the claimed invention has therefore not been established, as is specifically required to demonstrate a *prima facie* case of non-enablement.

Corn breeding is extremely advanced and well known in the art. This is due in large part to the fact that corn is one of the world's major food crops and largest seed crops. North American farmers alone plant *tens of millions of acres* of corn at the present time and there are *extensive national and international commercial corn breeding* programs. It is respectfully submitted that this is not true of petunias, sugar beets and tomatoes.

The Examiner has also not provided any basis other than personal opinion to suggest why the genetics of any of petunias, sugar beets or tomatoes are relevant to corn. Each of these plants are widely genetically diverged from maize – they are each classified as dicotyledonous plants whereas maize is a monocotyledonous plant. This distinction was noted by the Federal Circuit in *Plant Genetic Systems v. DeKalb Genetics Corp.*, in which a finding on non-enablement was affirmed because the claims read on both monocotyledonous and dicotyledonous plants, but were only enabled for dicotyledonous plants. 315 F.3d 1335 (Fed. Cir. 2003).

It therefore appears that the Examiner has improperly placed the burden to show enablement on Appellants while doubting numerous lines of evidence in support of enablement. The indication that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support. At the same time, the Examiner attempts to require Appellants to show why this is not true. While Appellants have nonetheless done so, it is respectfully noted that it is the *Office* that bears the burden of supporting its rejections. Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko*, 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir.

2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections are unsupported as required by the APA and contrary to the evidence submitted by Appellants.

The Examiner has also alleged that hybrid plants, seeds or parts thereof in claims 12-16 are not enabled. However, the Examiner has already acknowledged that the method of making a hybrid plant in claim 11 is enabled. Claim 12 is directed to the seed of claim 11. The rejection must therefore fail on its face – if the method of producing seed in claim 11 is enabled so is the seed produced by that method. Further, the specification describes *working examples* showing the production of *four hybrid plants*. No reason has been presented to conclude why this does not show enablement of the claims.

Claim 13 is directed to a plant produced by growing the seed of claim 12. As all that is required for this claim is mere germination of the seed in claim 12, this claim is also enabled. Claim 14 is directed to a seed produced by the plant of claim 13, which is inherently produced by growing the plant and is therefore also enabled.

Claim 15 is directed to an F1 hybrid plant produced by crossing the plant of claim 2 to *any* second plant. The plant of claim 2 has not been rejected and thus has been acknowledged to be enabled. All that the claim therefore requires is cross-pollinating the plant of claim 2 with any second plant. Once again, there is no basis to conclude why one of skill in the art could not do this, the most basic plant breeding step, particularly in light of the allowance of claim 11. Claim 16 is directed to a corn plant made by growing seed of claim 15, which again only requires germination of the seed and is enabled by claim 15.

All of the claims are therefore enabled and reversal of the rejection is thus respectfully requested.

Claims 17-18 concern a method for producing inbred LH321 seed comprising following the recited steps. Again, all that is required to complete the method is to follow the steps given in the claim, which themselves are known in the art and described in the specification. What was not known was the point of novelty, corn plant LH321, which has already been acknowledged to be enabled as set forth above. As such, the Examiner has failed to provide any basis to doubt the enablement of the claims.

Claims 19, 21, 24, 27 and 30-31 are all method claims that involve breeding corn plant corn plant LH321 according to the recited methods. Once again, all that is required to complete the method is to follow the steps given in the claim, which themselves are standard in the art. The only necessary starting material is corn plant LH321, which has already been acknowledged to be enabled as set forth above. While some of the steps involve use of a second corn plant, *any* different second corn plant can be used. What other plant or plants one chooses to cross with the claimed variety is therefore *completely irrelevant to enablement*, as any fertile corn plant could be used to produce an inbred corn plant derived from the corn line LH321. Enablement only requires that one of skill in the art be able to make and use the *claimed invention* without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). This has fully been done and no basis has been provided to conclude otherwise.

In view of the foregoing reversal of the rejection is respectfully requested.

C. Claims 6 and 26-28 Are Definite Under 35 U.S.C. §112, Second Paragraph

The Examiner rejects claims 6, 8 and 26-28 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out the subject matter which Applicants

regard as the invention. The rejection of claim 8 concerns a minor clerical error easily corrected by amendment and thus has not been appealed.

Claims 6 and 26-28 were rejected as allegedly broadening the scope of the claims from which they depend. In particular, it was stated that the independent claims from which these claims depend recite a plant with a given set of characteristics and claims 6 and 26-28 broaden this. However, this is incorrect. Both claims (1) *contain a reference to parent claim* from which they depend, (2) contain a *further limitation* of the subject matter claimed in the main claim, and (3) *incorporate all elements* of the claim from which they depend. For example, claim 6 recites the corn plant of claim 2 “further defined as comprising a gene conferring male sterility.” Claim 26, which claims 27 and 28 incorporate by reference, recites the corn plant of claim 2, “wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.”

Claims 6 and 26 therefore each specify an element that is *added* to the independent claim while still incorporating all of the limitations of the independent claim. Both claims are in proper dependent form pursuant to 37 C.F.R. §1.75(c) and are fully definite. Claims 27-28, which incorporate claim 26 by reference, are therefore also not indefinite. Reversal of the rejection is thus respectfully requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



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APPENDIX 1: APPEALED CLAIMS

6. (Amended) The corn plant of claim 2, wherein said plant is further defined as comprising a gene conferring male sterility.
12. A hybrid corn seed produced by the method of claim 11.
13. A hybrid corn plant, or parts thereof, produced by growing said hybrid corn seed of claim 12.
14. A corn seed produced by growing said corn plant of claim 13 and harvesting the resultant corn seed.
15. An F₁ hybrid seed produced by crossing the inbred corn plant according to claim 2 with another, different corn plant.
16. A hybrid corn plant, or its parts, produced by growing said hybrid corn seed of claim 15.
17. (Amended) A method for producing inbred LH321 seed, representative seed of which have been deposited under ATCC Accession No. _____, comprising:
 - a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred LH321, said collection also comprising seed of said inbred;
 - b) growing plants from said collection of seed;
 - c) identifying inbred parent plants;
 - d) controlling pollination in a manner which preserves the homozygosity of said inbred parent plant; and
 - e) harvesting the resultant seed.
18. (Amended) The process of claim 17 wherein step (c) further comprises identifying plants with decreased vigor.
19. A method for producing a LH321-derived corn plant, comprising:
 - a) crossing inbred corn line LH321, representative seed of said line having been deposited under ATCC accession number _____, with a second corn plant to yield progeny corn seed; and
 - b) growing said progeny corn seed, under plant growth conditions, to yield said LH321-derived corn plant.
21. The method of claim 19, further comprising:
 - c) crossing said LH321-derived corn plant with itself or another corn plant to yield additional LH321-derived progeny corn seed;

- d) growing said progeny corn seed of step (c) under plant growth conditions, to yield additional LH321-derived corn plants; and
 - e) repeating the crossing and growing steps of (c) and (d) from 0 to 7 times to generate further LH321-derived corn plants.
24. The method of claim 19, still further comprising utilizing plant tissue culture methods to derive progeny of said LH321-derived corn plant.
26. The corn plant, or parts thereof, of claim 2, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.
27. (Amended) A method for producing a corn plant that contains in its genetic material one or more transgenes, comprising crossing the corn plant of claim 26 with either a second plant of another corn line, or a non-transformed corn plant of the line LH321, wherein progeny are produced, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element.
28. Corn plants, or parts thereof, produced by the method of claim 27.
30. (Amended) A method for developing a corn plant in a corn plant breeding program using plant breeding techniques comprising employing a corn plant, or its parts, as a source of plant breeding material comprising: using the corn plant, or its parts, of claim 2 as a source of said breeding material.
31. (Amended) The method for developing a corn plant in a corn plant breeding program of claim 30 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.

APPENDIX 2: PENDING CLAIMS

1. Seed of corn inbred line designated LH321, representative seed of said line having been deposited under ATCC Accession No. _____.
2. A corn plant, or parts thereof, produced by growing the seed of claim 1.
3. Pollen of the plant of claim 2.
4. An ovule of the plant of claim 2.
5. A corn plant, or parts thereof, having all of the physiological and morphological characteristics of the corn plant of claim 2.
6. (Amended) The corn plant of claim 2, wherein said plant is further defined as comprising a gene conferring male sterility.
7. A tissue culture of regenerable cells from the corn plant of claim 2.
8. (Amended) The tissue culture according to claim 7, the cells or protoplasts of the tissue culture having been isolated from a tissue selected from the group consisting of leaves, pollen, embryos, roots, root tips, anthers, silks, flowers, kernels, ears, cobs, husks, and stalks.
9. (Amended) A corn plant regenerated from the tissue culture of claim 7, wherein the regenerated plant expresses all the morphological and physiological characteristics of inbred line LH321.
10. (Amended) A corn plant with all of the physiological and morphological characteristics of corn inbred LH321, wherein said corn plant is produced by a tissue culture process using the corn plant of claim 5 as the starting material for said process.
11. A method for producing a hybrid corn seed comprising crossing a first inbred parent corn plant with a second inbred parent corn plant and harvesting the resultant hybrid corn seed, wherein said first inbred parent corn plant or second said parent corn plant is the corn plant of claim 2.
12. A hybrid corn seed produced by the method of claim 11.
13. A hybrid corn plant, or parts thereof, produced by growing said hybrid corn seed of claim 12.
14. A corn seed produced by growing said corn plant of claim 13 and harvesting the resultant corn seed.

15. An F₁ hybrid seed produced by crossing the inbred corn plant according to claim 2 with another, different corn plant.
16. A hybrid corn plant, or its parts, produced by growing said hybrid corn seed of claim 15.
17. (Amended) A method for producing inbred LH321 seed, representative seed of which have been deposited under ATCC Accession No. _____, comprising:
 - a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred LH321, said collection also comprising seed of said inbred;
 - b) growing plants from said collection of seed;
 - c) identifying inbred parent plants;
 - d) controlling pollination in a manner which preserves the homozygosity of said inbred parent plant; and
 - e) harvesting the resultant seed.
18. (Amended) The process of claim 17 wherein step (c) further comprises identifying plants with decreased vigor.
19. A method for producing a LH321-derived corn plant, comprising:
 - a) crossing inbred corn line LH321, representative seed of said line having been deposited under ATCC accession number _____, with a second corn plant to yield progeny corn seed; and
 - b) growing said progeny corn seed, under plant growth conditions, to yield said LH321-derived corn plant.
21. The method of claim 19, further comprising:
 - c) crossing said LH321-derived corn plant with itself or another corn plant to yield additional LH321-derived progeny corn seed;
 - d) growing said progeny corn seed of step (c) under plant growth conditions, to yield additional LH321-derived corn plants; and
 - e) repeating the crossing and growing steps of (c) and (d) from 0 to 7 times to generate further LH321-derived corn plants.
24. The method of claim 19, still further comprising utilizing plant tissue culture methods to derive progeny of said LH321-derived corn plant.

26. The corn plant, or parts thereof, of claim 2, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.
27. (Amended) A method for producing a corn plant that contains in its genetic material one or more transgenes, comprising crossing the corn plant of claim 26 with either a second plant of another corn line, or a non-transformed corn plant of the line LH321, wherein progeny are produced, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element.
28. Corn plants, or parts thereof, produced by the method of claim 27.
30. (Amended) A method for developing a corn plant in a corn plant breeding program using plant breeding techniques comprising employing a corn plant, or its parts, as a source of plant breeding material comprising: using the corn plant, or its parts, of claim 2 as a source of said breeding material.
31. (Amended) The method for developing a corn plant in a corn plant breeding program of claim 30 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.